IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
	)	
Blackshear *et al.*	)	Group Art Unit: 1634
	)	
Application No. 10/049,586	)	Examiner: Sisson, B. L.
	)	
Filing Date: February 12, 2002	)	Confirmation No. 9700
	)	
For: TTP-RELATED ZINC FINGER DOMAINS AND METHODS OF USE	)	

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.
Customer Number 36339

Sir:

Applicant respectfully requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a Notice of Appeal. The review is requested for the reason(s) stated below. Briefly, it is the Applicant's position that the Examiner has not applied a proper understanding of the written description and utility requirements for a screening method for identifying inhibitors of a described mechanism.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 53-61, 71 and 72 were rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. The Examiner states that "[w]hile the specification has been found to comprise several examples, no example, or any other supporting disclosure, has been found to describe the claimed method in such full, clear, and concise language so as to reasonably suggest that applicant was in possession of the invention at the time of filing."

Applicants submit that the present rejection fails to take into account the proper understanding of what needs to be described in view of what is claimed, the proper understanding of the law of the written description requirement as it applies to the claimed method, and a proper application of that law to the claimed method. Applicants assert that (1) the specification *does* provide an adequate written description of the steps to be used in the claimed method according to the legal standard for the written description of a screening method and (2) the specification need not provide a written description of a compound *identified by* the claimed method because it is the *method* that needs to be described.

The Examiner has asserted that the specification lacks adequate written description since it does not "teach where any compound has been discovered/ identified as a result of practicing the claimed method." The first paragraph of 35 U.S.C. § 112 requires "a written description of the *invention*." Thus, written description of the claimed method requires description only of the act(s) to be performed because the act(s) to be performed in the claimed method is what the invention is. Whether those of skill in the art can succeed in carrying out the acts of the method and achieve the claimed results is solely a question of enablement. This is an *effect* of the method, not a step or act required to perform the method. Practicing the method so as to obtain the claimed effect is a feature of the *use* of the claimed method, not of the method step *per se*. Because how to use the claimed method is not a part of the written description requirement, such use is not a proper area of inquiry in assessing written description of the claimed method.

Applicants submit that for a method claim, the specification need only provide a written description of the method *steps* in order to comply with the written description requirement. The steps of the present methods include (1) contacting a sample containing TTP and ARE with a compound, and (2) detecting the binding between ARE and TTP. Applicants have described the critical materials for the claimed method (ARE and TTP) and the steps to be used. Further, while the Applicants contend that the method need not be actually practiced in an exemplary protocol to satisfy the written description requirement, the only step of the method that was not explicitly exemplified was the contacting step, which is both variable and routine.

Furthermore, as the choice of compound to apply to the screening method is variable, exemplification of the method, wherein a specific compound is identified and described, could not show definitively that any other compound would likewise be identified. Thus, if, *arguendo*, exemplification were required for written description, then a provided working example could

only be a description of the use of the method to identify *that* compound. Although this appears to be an implication of the present rejection, applicants are confident that this is not how the Patent Office intends its analysis of written description for a screening method to be applied.

In fact, the Court of Appeals for the Federal Circuit has supported the Applicants' position that the written description requirement for a screening claim can be satisfied without a description of compounds identified by said method. In *University of Rochester v. G.D. Searle & Co.* 69 USPQ2D (BNA) 1886 (Fed. Cir. Feb. 13, 2004) (hereafter *Rochester*), the plaintiffs had both a claim to (1) a screening method for identifying, i.e., screening for, a COX-2 inhibitor and (2) a method of using a COX-2 inhibitor to treat inflammatory disease. However, at the time the application was filed, the plaintiffs had not actually identified a COX-2 inhibitor using the provided screening method. The court therefore decided that the inventor had failed to sufficiently describe the method of using the compound such that one of ordinary skill in the art would recognize that they actually possessed the method of using the compound at the time of filing. However, the Court found that the *Rochester* specification did in fact comply with the written description requirement for claims to assay methods, stating that "[t]he only claims that appear to be supported by the specification are claims to assay methods, but those claims were already issued in the '479 patent." *Id* at 928. The Court came to this conclusion even in the absence of the actual practice of a step of contacting the assay components with any putative COX-2 inhibitor, or the actual identification of any COX-2 inhibitor.

Thus, according to the reasoning in *Rochester*, the written description requirement for a screening method is satisfied by a full, clear, and concise description of a biological mechanism coupled with a description of the steps necessary to determine if a candidate composition modulates the properties of said biological mechanism. The present screening method claims are based on the fully, clearly and concisely described biological mechanism of the interaction between a TTP zinc finger domain and an ARE (see further description below). Thus, the legal requirements, when properly applied to the present facts, support a finding that the present screening method claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Thus, the Applicants believe that the present rejection fails to establish a *prima facie* case for lack of written description and respectfully requests that the rejection be withdrawn.

Rejection Under 35 U.S.C. § 101

Claims 53-61, 71 and 72 were rejected under 35 U.S.C. § 101 as allegedly not supported by either a credible asserted utility or a well-established utility. The Examiner notes that "[i]n order for the claimed method to have utility, the method must give rise to a product that in turn has utility, or has been shown to give rise to a product or method that in turn has utility."

The Examiner argues that "the specification does not teach where any compound has been identified by the claimed method, much less that the product so identified has in fact been found to satisfy the utility requirement, either directly or indirectly." This is not a proper statement of the requirement for providing a utility for a screening method. It is the method itself, i.e., a method of finding a compound that can or may interfere with binding between TTP and ARE, for which utility must be shown. There is no requirement that a compound be identified for a screening method to have utility. A method of looking for a compound that can or may impact a known disease pathway/mechanism has a real world utility as a tool for identifying such compounds. Those of skill in the art will recognize that a method of finding a compound that interferes in the disclosed pathway is valuable and has utility.

Further, as the choice of compound to apply to the screening method is variable, exemplification of the method, wherein a specific compound is identified and described, would not and could not be evidence that any other compound existed. Thus, the implication that the utility of a screening method depends on the actual identification of a useful compound, does not make sense. Rather it is the capability of the method to identify such a compound, should one exist, that is the basis for utility of a screening method. Applicants establish this capability through the teaching of the mechanism of TTP and ARE interaction.

Further, as stated by the Examiner, it is not required that the Applicants demonstrate a utility, only that the Applicants assert a credible utility. Applicants assert that the invention features a method of treating granulocytopenia in a subject (page 3, line 12) and provide credible support for this assertion based on the importance of the mechanism on which the method is based and the credible real world uses for compounds that might be identified by the method (page 20, lines 12-29). As the Examiner has cited no specific basis to contradict Applicants' assertion of utility, it should be accepted as sufficient. The withdrawal of this rejection is therefore respectfully requested.

Rejection Under 35 U.S.C. § 112, first paragraph

Claims 53-61, 71 and 72 were also rejected under 35 U.S.C. § 112, first paragraph as allegedly "not supported by either a credible asserted utility or a well-established utility" such that "one skilled in the art clearly would not know how to use the claimed invention." Applicant's traverse this rejection at least for the reasons stated above in response to the rejection under 35 U.S.C. § 101. Specifically, as the Examiner has cited no specific basis to contradict Applicants' assertion of utility, it should be accepted as sufficient. Further, as any analysis of a claim under 35 U.S.C. § 112, first paragraph, relating to the use of the claimed subject matter, need only meet the standards of the utility requirement of 35 U.S.C. § 101, a 35 U.S.C. § 112, first paragraph, rejection should not be imposed or maintained unless an appropriate basis exists for imposing a rejection under 35 U.S.C. § 101 under these guidelines.

Payment Form PTO-2038 authorizing payment in the amount of $620.00, representing $500.00 for the Appeal fee pursuant to 37 C.F.R. §41.20(b)(1) and $120 for the fee under 37 C.F.R. § 1.17(a)(1) for a Request for One Month Extension of Time, is enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

P. Brian Giles
Registration No. 57,896

NEEDLE & ROSENBERG, P.C.
Customer Number 36339
(678) 420-9300
(678) 420-9301 (fax)